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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,140	11/16/1999	BEKA SOLOMON	27/150	3910

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EXAMINER	
LYLES, JOHNALYN D	
ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/441,140	SOLOMON, BEKA	
	Examiner	Art Unit	
	Johnalyn Lyles	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/17/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 150-209* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 150-209* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-4 and 150-209* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 November 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/23/04, 4/19/04*, 8/9/04, 8/18/04, 3/17/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Examiner of U.S. Patent Application No. 09/441,140 has changed. In order to expedite the correlation of papers with the application please **direct all future correspondence to Examiner Lyles**, Technology Center 1600, Art Unit 1649.

2. The amendment filed on 3/17/2005 under 37 CFR 1.312 has been entered into the record and has been fully considered. Claims 5-149 have been cancelled. Claims 1-4 and 150-209 are pending.

3. The statement under 37 C.F.R. §1.173(c) has been noted by the Examiner.

4. The statement under 37 C.F.R. §1.178(b) has been noted by the Examiner.

5. The statement under 37 C.F.R. §1.175(b)(1) has been noted by the Examiner.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. As a result of Applicant's amendment, all objections and rejections, not reiterated herein, have been **withdrawn** by the examiner.

Maintained Rejections

Claim Rejections - 35 USC § 102

Claims 150-151, 156-157, 162-163, and 168-169 remain rejected under 35 U.S.C. 102(a) as being anticipated by Bickel *et al.* (*Bioconiugate* 5(2): 119-125, March/April 1994) for the reasons as set forth at pp. 3-5 ¶11-17 in the previous Office Action (17 September 2004).

Applicant traversed the rejection of the claims in the Response filed 9 August 2004 on the following grounds: (a) the claims require the antibody to be in a "unit dosage" and (b) *In re Ngai* is non-analogous case law and does not support the rejection.

In the instant case, Applicant has provided a formulation of a known monoclonal antibody, the AMY33, as a "unit dosage." *In re Ngai*, 70 USPQ2d 1862 (CA FC 2004) discusses the instance where a claim directed to a kit for performing the method of normalizing and amplifying ribonucleic acids was properly rejected as anticipated by prior art. Even though the content of instructions in the claimed kit differed from the instructions in the prior art, addition of the new set of instructions into a known kit merely teaches a new use for an existing product in that the instructions do not interrelate with the kit so as to produce a new product and the addition of printed matter to an existing product will not distinguish the invention from the prior art in terms of patentability if the printed matter is not functionally related to the product.

As noted in *In re Ngai,* printed matter added to an existing product will not distinguish the invention from the prior art in terms of patentability if the printed matter is

not functionally related to the product. Herein, the Examiner treats the limitation of "unit dosage" as implied instructions, written in the form of a claim preamble. This limitation does not affect the physical properties of the claimed antibody. It is no more than a "mixture" or "packaging" in the form of a solution or composition. As evident from Bickel *et al.*, therapeutic use is not the only applicable use of the AMY-33 monoclonal antibody and therefore cannot be limiting.

In addition, a preamble is not a limitation when the claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim (See MPEP §2112[R-2]). The claims recite functional properties assigned to the claimed antibody including "inhibits β-amyloid aggregation" and/or "maintains soluble β-amyloid solubility;" however, the instantly claimed antibody is the same AMY33 antibody taught by Bickel *et al.* Although Bickel *et al.* is silent on said properties, since a compound and all of its properties are inseparable, the antibodies are the same antibodies (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)).

Furthermore, the Examiner notes that the antibodies raised against the first 28 amino acids of β-amyloid inherently have "chaperone" or anti-aggregating properties as evidenced by Solomon, *Expert Opin Biol Ther*, December 2002, 2(8):907-917. Solomon teaches that antibodies targeting the N-terminus of Aβ (residues 1-28) have anti-aggregating properties including solubilization of existing aggregates and inhibition of aggregation (See p. 909). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of the invention, but only that the subject matter is in fact inherent in the prior art reference [See *Schering v.*

Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003)]. Therefore, by adding the "unit dosage" or "pharmaceutical composition" limitation, Applicant is providing a new use for an existing product.

Bickel *et al.* teach a solution of the human monoclonal antibodies in standard ELISA buffer. The recitation in the claims "pharmaceutical formulation" and "unit dosage" is interpreted as an intended use and is not given patentable weight in this art rejection. Also, use of the composition of Bickel *et al.* is not inconsistent with such treatment.

Applicant's withdrawal of the grounds of traversal concerning Tris buffer is noted.

Claims 150-1, 156-7, 162-3, and 168-9 remain rejected under 35 U.S.C. 102(b) as being anticipated by Stern *et al. Am J Pathol.*, May 1989, 134(5):973-8 for the reasons as set forth at pp. 18-26 ¶5-8 in the previous Office Action (9/17/2004).

Applicant traversed the rejection of the claims in the Response filed 17 September 2004 on the following grounds: (a) the claims require the antibody to be in a "unit dosage" and (b) Stern et al. does not use its antibody preparation as a therapeutic and does not take steps to ensure that the composition would be pharmaceutically acceptable.

In the instant case, Applicant has provided a formulation of known monoclonal antibodies (Table 1), as a "unit dosage." *In re Ngai*, 70 USPQ2d 1862 (CA FC 2004) discusses the instance where a claim directed to a kit for performing the method of normalizing and amplifying ribonucleic acids was properly rejected as anticipated by

prior art. Even though the content of instructions in the claimed kit differed from the instructions in the prior art, addition of the new set of instructions into a known kit merely teaches a new use for an existing product in that the instructions do not interrelate with the kit so as to produce a new product and the addition of printed matter to an existing product will not distinguish the invention from the prior art in terms of patentability if the printed matter is not functionally related to the product.

As noted in *In re Ngai,* printed matter added to an existing product will not distinguish the invention from the prior art in terms of patentability if the printed matter is not functionally related to the product. Herein, the Examiner treats the limitation of "unit dosage" as implied instructions, written in the form of a claim preamble. This limitation does not affect the physical properties of the claimed antibody. It is no more than a "mixture" or "packaging" in the form of a solution or composition. As evident from Stern *et al.*, therapeutic use is not the only applicable use of the monoclonal antibodies and therefore cannot be limiting.

A preamble is not a limitation when the claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim (See MPEP §2112[R-2]). The claims recite functional properties assigned to the claimed antibody including "inhibits β-amyloid aggregation" and/or "maintains soluble β-amyloid solubility;" however, the antibodies taught by Stern *et al.* falls within the genus of antibodies as instantly claimed. Although Stern *et al.* is silent on said properties, a compound and all of its properties are inseparable; thus, the antibodies are

taken to be the same antibodies (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)).

Furthermore, the Examiner notes that the antibodies raised against the first 28 amino acids of β-amyloid inherently have "chaperone" or anti-aggregating properties as evidenced by Solomon, *Expert Opin. Biol. Ther.*, December 2002, 2(8):907-917. Solomon teaches that antibodies targeting the N-terminus of Aβ (residues 1-28) have anti-aggregating properties including solubilization of existing aggregates and inhibition of aggregation (See p. 909). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of the invention, but only that the subject matter is in fact inherent in the prior art reference [See *Schering v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003)]. Therefore, by adding the "unit dosage" or "pharmaceutical composition" limitation, Applicant is providing a new use for an existing product. Therefore, by adding the "unit dosage" or "pharmaceutical composition" limitation, Applicant is providing a new use for an existing product.

Stern *et al.* teach a solution of the monoclonal antibodies in standard ELISA buffer. The recitation in the claims "pharmaceutical formulation" and "unit dosage" is interpreted as an intended use and is not given patentable weight in this art rejection. Also, use of the composition of Stern *et al.* is not inconsistent with such treatment.

Concerning (b), Applicant refers to Stern *et al.*'s alleged failure to practice method steps. The instant rejection concerns a product, and as such, Stern *et al.*'s alleged failure to attempt therapy is not relevant. It has been established by the courts

that a product inherently possesses characteristics of that product (i.e. including the amino acid sequence of a protein); see, for example. *Ex parte Gray*, 10 USPQ 2d; *In re Best*, 195 USPQ 430). Further, according to the MPEP § 2112 [R-2], Requirements of Rejection Based on Inherency; Burden of Proof,

> "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims.
>
> See *Ex parte Gray,* 10 USPQ 2d 1922 (1989); *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Accordingly, since the issue in the instant case is whether the prior art factor is identified or patentably in distinct from that of the material on appeal, Appellants have the burden of showing that inherency is not involved. See MPEP § 2113 [R-1] Product-by-Process Claims, *Ex parte Gray*, 10 USPQ 2d 1922 (1989) and *In re Best*, 195 USPQ 430 (CCPA 1976). Moreover, when the product in a product-by-process claim is the same or obvious by a product of the prior art, the claim is unpatentable, although the prior art product was made by a different process. See MPEP § 2113, *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985), and *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). Finally, it is noted that the courts have held that when the prior art product reasonably appears to be the same as that claimed but differs by the process in which it is produced, a rejection of this nature is eminently fair and the burden is upon the Appellants to prove, by comparative evidence, a patentable

difference. See MPEP § 2113 and *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

New Objections, and/or Rejections New, Necessitated by Amendment

Claim Objections

Claims 1-4 are objected to because of the following informalities: the Markush group contains multiple elements and two of the elements appear to be listed as one wherein "genetically engineered antibody" and "antigen binding fragment" are recited. Separation by a comma and insertion of the article "an" before the element "antigen binding fragment" are suggested.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 150-173 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description requirement**. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The claims recite the limitation of "unit dose," and the instant specification of the US patent does not contain any support, explicitly, implicitly, or inherently for this new limitation.

Applicant argues on page 13-17 and 20 that the language of the claims complies with the written description requirement and the concept of a pharmaceutical formulation for therapeutic administration must necessarily and implicitly support that such formulation will be in unit dosage form. Further, Applicant argues that "formulation" includes the concept of "packaging," which would require that the protein pharmaceutical be packaged in unit dosage form.

Applicant's arguments filed 3/17/2005 in the Remarks have been fully considered but they are not persuasive. As noted by Applicant, a formulation includes "a mixture or prescribed recipe for packaging a protein pharmaceutical." Therefore, the term may include a recipe for packaging but does not require that the protein be packaged in unit dosage form. For example, the formulation or packaging may be a multidose formulation.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors relevant to this discussion include the quantity of experimentation necessary, the lack of working

examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims.

While the specification discloses the target polypeptide, β-amyloid, with no prescribed activity, the specification fails to teach the bioactivity of the target molecule as claimed. In the instant case, what is lacking is a description of any embodiments with a clear perceived function to inhibit and retain bioactivity. The specification does not provide enablement for selection of anti-aggregation molecules that do not inhibit the native function. The claims are directed toward selecting an anti-aggregation molecule for any peptide that aggregates. The specification does not teach a method of selecting any anti-aggregation molecule, which binds to a bioactive native target polypeptide epitope and is noninhibitory to the biological activity of the target polypeptide. The specification fails to provide any exemplary evidence of any function for every polypeptide as claimed such that one of skill in the art can make and use the invention as claimed. The claim requires testing the polypeptide for bioactivity thereby selecting an anti-aggregation molecule that when coupled to the target maintains activity. The specification does not enable selecting a molecule capable of inhibiting aggregation and retaining function. Since the scope of "target polypeptide" is deemed to be so inclusive, the scope of enablement provided by the specification is not commensurate in scope with the claims.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made and still maintain activity/utility is unpredictable and the

experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986). Thus, the skilled artisan cannot readily make and use the claimed method without further undue experimentation.

Claim Rejections - 35 USC § 102

Claims 152, 158, 164, and 170, 173-175, 178-180, 183-184, 187-189, 192-193, 196-198, 201-202, 205-207 are rejected under 35 U.S.C. 102(a) as being anticipated by Bickel *et al.* (*Bioconiugate* 5(2): 119-125, March/April 1994) for the reasons as set forth at pp. 3-5 ¶11-17 in the previous Office Action (17 September 2004) and as noted above under "Maintained Rejections". Bickel *et al.* teach a solution of the **human monoclonal antibodies** in standard ELISA buffer. The recitation in the claims "pharmaceutical formulation" and "unit dosage" is interpreted as an intended use and is not given patentable weight in this art rejection. Also, use of the antibodies of Bickel *et al.* is not inconsistent with therapeutic utility.

Claims 150-152, 156-158, 162-164, 168-170, 173-175, 178-180, 183-184, 187-189, 192-193, 196-198, 201-202, and 205-207 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaskin *et al.*, J Exp Med, 1 April 1993, 177(4):1181-1186 as evidenced by Solomon Expert Opin Biol Ther, 2(8):907-917. Gaskin et al. teach four human monoclonal antibodies, which bind an epitope obtainable from residues 1-28 of human Aβ thus meeting the claim limitations of claims 150-2, 156-8, 162-4, 168-70, 173-5, 178-80, 183-4, 187-9, 192-3, 196-8, 201-2, and 205-7 (Figure 1; p. 1182).

A preamble is not a limitation when the claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim (See MPEP §2112[R-2]). The claims recite functional properties assigned to the claimed antibody including "inhibits β-amyloid aggregation" and/or "maintains soluble β-amyloid solubility;" however, the antibodies taught by Gaskin *et al.* fall within the genus of antibodies as instantly claimed. Although Gaskin *et al.* is silent on said properties, a compound and all of its properties are inseparable; thus, the antibodies are taken to be the same antibodies (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). Therefore, by adding the "unit dosage" or "pharmaceutical composition" limitation, Applicant is providing an intended use for an existing product.

Furthermore, the Examiner notes that the antibodies raised against the first 28 amino acids of β-amyloid inherently have "chaperone" or anti-aggregating properties as evidenced by Solomon, *Expert Opin. Biol. Ther.*, December 2002, 2(8):907-917. Solomon teaches that antibodies targeting the N-terminus of Aβ (residues 1-28) have anti-aggregating properties including solubilization of existing aggregates and inhibition of aggregation (See p. 909). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of the invention, but only that the subject matter is in fact inherent in the prior art reference [See *Schering v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003)]. Therefore, by adding the "unit dosage" or "pharmaceutical composition" limitation, Applicant is providing a new use for an existing product previously within the scope of

unit dose and pharmaceutical composition as there are no other administrative elements or properties.

The standard antibody solution for performing immuocytochemistry (including ELISA) is PBS which is 1 MM KH2PO4, 3 mM Na2HPO4 8 7H2), pH 7.4, and 155 mM NaCl (see GIBCO Media Formulations from Invitrogen website; retrieved 9/03/2004). Therefore, PBS the standard ELISA solution is almost identical to physiological salt molarity and pH (See Moffett et al. (1993) Human Physiology, 2nd ed., inside cover). Gaskin *et al.* teach a solution of human monoclonal antibodies in standard ELISA buffer. The recitation in the claims "pharmaceutical formulation" and "unit dosage" is interpreted as an intended use and is not given patentable weight in this art rejection. Also, use of the composition of Gaskin *et al.* is not inconsistent with such treatment.

Claims 150, 151, 156,157, 162, 163, 168-169, 178-9, 187-188, 196-197, and 205-206 are rejected under 35 U.S.C. 102(a) as being anticipated by Walker *et al.*, *Journal of Neuropathology and Experimental Neurology*, July 1994, 53(4):377-383 as evidenced by Solomon Expert Opin Biol Ther, 2(8):907-917. Walker *et al.* teach a monoclonal antibody 10D5, a murine IgG1, kappa light chain (whole IgG and/or Fab fragments) specific for residues 1-16 of Aβ. The reference teaches a pharmaceutical composition of 10D5 in sterile solution, which is administered to rhesus and squirrel monkeys, thus meeting the limitations of claims 150-1, 156-7, 162-3, 168-9, 178-9, 187-188, 196-197, and 205-206.

A preamble is not a limitation when the claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder

of the claim (See MPEP §2112[R-2]). The claims recite functional properties assigned to the claimed antibody including "inhibits β-amyloid aggregation" and/or "maintains soluble β-amyloid solubility;" however, the 10D5 antibody taught by Walker *et al.* falls within the genus of antibodies as instantly claimed. Although Walker *et al.* is silent on said properties, a compound and all of its properties are inseparable; thus, the antibodies are taken to be the same antibodies (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). Therefore, by adding the "unit dosage" limitation, Applicant is providing a new use for an existing product.

Furthermore, the Examiner notes that the antibodies raised against the first 28 amino acids of β-amyloid inherently have "chaperone" or anti-aggregating properties as evidenced by Solomon, *Expert Opin. Biol. Ther.*, December 2002, 2(8):907-917. Solomon teaches that antibodies targeting the N-terminus of Aβ (residues 1-28) have anti-aggregating properties including solubilization of existing aggregates and inhibition of aggregation (See p. 909). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of the invention, but only that the subject matter is in fact inherent in the prior art reference [See *Schering v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003)]. Therefore, by adding the "unit dosage" or "pharmaceutical composition" limitation, Applicant is providing an intended use for an existing product.

Walker *et al.* teach a solution of the monoclonal antibodies in sterile saline solution. The recitation in the claims "pharmaceutical formulation" and "unit dosage" is interpreted as an intended use and is not given patentable weight in this art rejection.

Also, use of the composition of Walker *et al.* is not inconsistent with such treatment as it was successfully administered to monkeys.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 150-209 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Becker *et al.*, European patent application, EP 0613007 A2, filed 2/18/94 in view of Bickel *et al., Bioconiugate* 5(2): 119-125, March/April 1994 or Gaskin *et al.*, *J Exp Med*, 1 April 1993, 177(4):1181-1186.

Becker *et al.* teach pharmaceutical formulations containing antibodies having specificity for β-amyloid peptide. The reference teaches the peptides contain just the first 40 amino acids of the β-amyloid peptide (β1-40). The reference teaches antibodies and fragments of antibodies, including chimeric, humanized, veneered, resurfaced or CDR-grafted antibodies, single-chain antibodies as well as human monoclonal antibodies and genetically engineered monoclonal antibodies (p. 4 columns 5-6). The antibodies disclosed are presumed to recognize an epitope within residues 1-28 of beta amyloid or to be obtainable using residues 1-28 of beta amyloid as an immunogen.

As noted above, a preamble is not a limitation when the claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim (See MPEP §2112[R-2]). The claims recite functional properties assigned to the claimed antibody including "inhibits β-amyloid aggregation" and/or "maintains soluble β-amyloid solubility;" however, the antibodies taught by Becker *et al.* fall within the genus of antibodies as instantly claimed (See Frenkel et al., Journal of Neuroimmunology, 1998, 88:85-90). Although Becker *et al.* is silent on said properties, a compound and all of its properties are inseparable; thus, the antibodies are taken to be the same antibodies (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). Therefore, by adding the "unit dosage" or "pharmaceutical composition" limitation, Applicant is providing an intended use for an existing product.

Furthermore, it would have been obvious to use the antibodies of Bickel and Gaskin to produce pharmaceutical formulations wherein the antibody is genetically

engineered or a single chain antibody as taught by Becker *et al.* and well-established in the art.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Solomon *et al.*, 1989, Biochemistry, 28:1235-1241. Solomon *et al.* teach mixing a denatured target polypeptide, carboxypeptidase A (CPA), with a monoclonal antibody under conditions allowing for aggregation (pg 1236). Testing for bioactivity demonstrates that the monoclonal antibody used does not inhibit peptidase or esterase activities; thus, CPA maintains bioactivity (pg1240). Although the reference is silent to the monoclonal antibodies preventing carboxypeptidase A aggregation, this limitation in the preamble is an inherent property of the instant monoclonal antibodies.

Conclusion

The Examiner notes Figure 1 in Barrow *et al.*, (J Mol Biol, June 20, 1992, 225(4):1075-93) for the definition of Aβ fragments.

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Johnalyn Lyles whose telephone number is 571-272-3433. The examiner can normally be reached on M-F 8 am - 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jdl

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